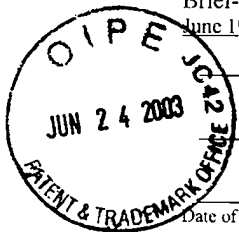


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PATENT
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Signature

June 19, 2003

Date of Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

BRIAN H. SILVER AND GOTTHILF WENIGER

Serial No. 08/203,672

Filed: February 28, 1994

Title: DISPOSABLE MILK COLLECTING BAG FOR A
BREAST PUMP

Examiner: Trinh, V.

Group Art Unit: 2814

**APPLICANTS' BRIEF IN SUPPORT OF APPEAL TO THE BOARD OF PATENT
APPEALS AND INTERFERENCES**

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APPEAL BRIEF

I. REAL PARTY IN INTEREST

The application is assigned to Medela Holding AG, which assignment was recorded at Reel 012922 and Frame 0453.

II. STATUS OF CLAIMS

Claims 8-14, 19 and 20-26 are pending. Claims 8-14 and 19 are indicated as being allowed. Claims 20-26 stand rejected. Claims 20-26 are on appeal.

III. STATUS OF THE AMENDMENTS

The Claims as amended after the Examiner's Final Office Action dated September 25, 2002, are presented in an Amendment filed concurrently herewith. (See Appendix A).

IV. SUMMARY OF THE INVENTION

The present invention is directed to a sanitary disposable bag for attachment to a breast milk pump for receiving, containing and dispensing breast milk. The bag can be easily and efficiently manufactured, packaged and used. (Specification, page 2, lines 3-5 (Appendix B)) As discussed in detail in the Background of the Invention, breast milk pumps are well known in the art, and generally comprise a hood that is sized and shaped to fit over a breast, a source of vacuum connected to the hood for generating an intermittent pressure change (vacuum) within the hood, and a receptacle for receiving the expressed milk. (Specification, page 1, lines 8-12)

During use, breast milk pumps generate the intermittent pressure change within the hood, with the hood encompassing the nipple and a substantial amount of the breast. (Specification, page 1, lines 16-19) The intermittent action of the pump serves to pull on the breast to draw it with the narrowing funnel of the hood. (Specification, page 1, lines 19-22) The action of the pump extracts milk in a manner to simulate suckling. (Specification, page 1, lines 19-22) As the milk is extracted, it flows through the hood, typically into a container. (Specification, page 1, lines 23-24)

Rigid milk containers are most commonly used as the containers for collecting and storing breast milk with breast milk pumps. (Specification, page 1, lines 27-28) However, it would be desirable to use disposable plastic bags as the containers. (Specification, page 1, lines 28-29) Disposable plastic bags are far less costly than rigid containers thereby enabling a large number of feedings to be stored in a more cost effective manner. (Specification, page 3, lines 3-5) Such disposable plastic bags also take up less space. *Id.*

The present invention includes an improved flexible plastic bag specifically adapted to contain milk. (Specification, page 2, lines 6-8) The bag is formed by two sheets of plastic constituting a front and a back sheet in facial engagement and joined to each other by a series of

seals. (Specification, page 2, lines 8-12) The configuration of the two sheets yields a hermitically sealed liquid containing portion of the bag. *Id.*

One important feature of the invention is a writing area formed integral with the bag by the same sealing technique, but with the existing area isolated from the liquid containing portion of the milk of the bag. (Specification, page 2, lines 12-16) The bag can, accordingly, be written on more easily than bags with milk beneath the writing area, and without risk of puncturing the milk containing portion. (Specification, page 2, lines 16-18)

The invention includes an opening in the liquid containing portion of the bag for attachment to a breast milk pump. (Specification, page 2, lines 19-21) The opening is releasably sealed using a peelable coating, a weak heat seal, or other appropriately releasable fastening methods, so that the bag can be provided to the nursing mother hermetically sealed, but can be readily peeled open for attachment to the breast milk pump. (Specification, page 2, lines 21-25) The invention may further include a tie that can be laced through at least two holes provided at substantially opposite sides of the bag opening. (Specification, page 2, lines 26-28) The laced tie is twisted upon itself to reseal the opening when the bag is removed from the breast milk pump, and stored. (Specification, page 2, lines 28-30)

An important feature that the inventive bag may further include is a pour spout formed integral with, and separate from the foregoing bag opening. (Specification, page 2, lines 31-33) The pour spout can be torn open to pour milk from the bag, and it is preferably formed along the corner of the bag adjacent the writing area previously discussed. (Specification, page 2, lines 33 to page 3, line 2) A notch in the side of the bag located near the pour spout serves to facilitate the opening of the spout. (Specification, page 3, lines 1-2)

In sum, the breast milk bag of the present invention can be hermetically sealed, and thus remain sterile prior to use. (Specification, page 3, lines 6-7) In addition, after breast milk is

expressed into the bag, the bag opening can be resealed as with the laced tie, and the breast milk can thereby be sanitarily stored for later use. (Specification, page 3, lines 8-10) The provision of a writing area formed integral with the bag but isolated from the liquid containing portion of the bag, facilitates writing and diminishes the risk of puncturing the bag during writing. (Specification, page 3, lines 10-15) With the writing area formed adjacent to a pour spout, as shown in FIGS. 3 and 4, the writing area further serves as a stop for the tearing action when a user wishes to open the breast milk bag, thus improving the formation of the spout and making the inventive milk bag simple and efficient to use. (Specification, page 3, lines 13-18; page 7, lines 3-20)

V. ISSUES

Whether the invention as claimed in Claims 20-23 was improperly rejected under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 3,905,477 to Graham ("Graham").

Whether the invention as claimed in Claims 25-26 was improperly rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,600,104 to Yanase ("Yanase").

Whether the invention as claimed in Claims 20-24 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over Yanase in view of Graham.

VI. GROUPING OF CLAIMS

The Claims do not stand or fall together. Since each claim has a different scope, each has different reasons for allowability over the cited references. However, because many of the claims include similar limitations that alone differentiate those claims over the prior art, some of the claims may be discussed in logical groups. For purposes of the rejections, the claims are grouped as follows:

Group A

Claims 20-23 are directed to a disposable bag. The bag is adapted to contain breast milk and includes a flexible closed enclosure defining a chamber adapted to contain breast milk. The enclosure is permanently sealed except at one portion which includes a releasably sealed bag access adapted to seal the bag in a first position, and is also adapted to selectively allow in a second position attachment to a breastpump and allow the breast milk to be introduced into the chamber when it is desired to use the bag. Once in the second position, the breast milk can be received in the bag, wherein the bag comprises a section located remote from the enclosure and adapted for receiving thereon information about contents of the bag.

Claims 21-23 depend from Claim 20 and further define the section for writing a date of filling (Claim 21), a volume of filling (Claim 22) and the limitation that the bag is formed of a plastic tube permanently closed at one end (Claim 23).

Group B

Claim 24 is directed to a disposable bag as set forth in the Claims of Group A in combination with a bag holder.

Group C

Claims 25 and 26 are directed to a method of handling breast milk using the disposable bag as set forth in the Claims of Group A.

VII. ARGUMENT

- A. Independent Claim 20 and Dependent Claims 21-23 Should Be Allowed Because The Examiner's Rejection Based Upon Anticipation by U.S. Patent No. 3,905,477 ("Graham") Does Not Address The Patentably Distinguishing Features Of The Invention.

The Examiner rejected Claims 20-23 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 3,905,477 to Graham ("Graham"). Because Graham does not disclose each and every element of the invention to which Claim 20 is directed, Claim 20 and the Claims which depend from Claim 20 (Claims 21-23) should be allowed.

Claim 20 is directed to a disposable bag adapted to contain breast milk. The bag includes a flexible closed enclosure defining a chamber to contain breast milk. The enclosure is permanently sealed except at one portion which includes a releasably sealed seam bag access. The bag access is adapted so that the bag is sealable in a first position and, when use of the bag is desired, selectively allows, in a second position, milk to be introduced in the chamber. The bag includes a section, located remote from the enclosure, adapted for receiving information about the bag contents.

The Examiner makes the following characterizations with respect to Graham. The Examiner opines that Graham discloses a disposable bag 11 which is permanently sealed except at one portion at the top end closure 25 thereof. The portion comprises a bag access 20 adapted to substantially seal the bag in a first position thereof by a plug or a clamp means but also adapted to selectively allow in a second position thereof the liquid to be introduced in the chamber/enclosure 27 having a front side and a back side, a seal 10 to seal the front and the back side together, and a section or a writing area 23, wherein the writing area 23 forms integral with the bag 11 by the seal 9 and isolates or remotes from a liquid containing portion or enclosure 27. (See Office Action, dated September 25, 2002)

Graham clearly does not anticipate Claim 20: Graham teaches a pouch having far different and a far greater number of elements. To illustrate, Graham does not teach a section of a disposable bag for receiving thereon information about a content of the bag. Instead, Graham discloses (Col. 3, lines 20-27) a pressure sensitive surface label 23 disposed in compartment 21. The installation of the label 23 must of course be made before the second of the seals 17, 19 is applied and in the connection it may be advantageous in the interest of maintaining sterility to make the seal 19 first, insert the label 23 into its compartment 21 from the bottom end of the pouch and then apply the end closure seal 17.

In contrast, the writing area of the present invention is a writing area formed integral with and from the bag by the same sealing technique as the enclosure, so that - while the writing area is isolated from the liquid containing portion of the milk of the bag - the area is on the bag and permits information to be written on it more easily than bags with milk beneath the writing area, and without risk of puncturing the milk containing portion. (Specification, page 2, lines 16-18) In further contrast, the writing area of the present invention does not require an outer seal to be formed as does Graham (Seal 17) and thus, further distinguishes from Graham.

From this description, it can be seen that the label of Graham is not structurally the same as that of the writing area of the present invention. In Graham, a label is contained within a compartment formed by a separate enclosure 21. The label of Graham contains more elements, requires more steps to prepare, and is more laborious and expensive to construct. Graham does not teach or suggest the writing section of the present invention.

The Examiner never directly addresses the differences between the teachings of Graham and the invention that is the subject of Claim 20. The Examiner simply implies, but never states with respect to Claim 20, that the label 23 of Graham is the same as the section of the present invention on which information about the content of the bag is receivable.

Graham also does not disclose the simplified releasably sealed seam bag access of Claim 20. Graham instead provides for a more complex ingress and egress of fluid by way of a tube 29, which may be opened and closed by way of a clamp or plug. (Specification, Col. 3, lines 37-42) Graham teaches that the pouch requires a second tube 31 to vent the pouch interior during the use of tube 29. (Col. 3, lines 42-48) It is clear that the tube/clamp/plug disclosure of Graham is not the same structurally as the releasable seam of the present Claim 20 and does not function in the same way or accomplish the same thing as the releasable seam of the present Claim 20. Graham discloses a tube input 29 and a tube vent 31 but not a bag access which permits attachment to a breastpump as in the present invention.

Given that the invention to which independent Claim 20 is directed is not taught by and therefore not anticipated by Graham, Claims 21-23 which are dependent on Claims 20 are likewise not anticipated by Graham.

- B. Independent Claim 25 and dependent Claim 26 should be allowed because the Examiner's Rejection Based Upon Anticipation by U.S. Patent No. 4,600,104 ("Yanase") Does Not Address The Patentably Distinguishing Features Of The Invention.

The Examiner rejected Claims 25-26 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent No. 4,600,104 to Yanase ("Yanase"). Because Yanase does not disclose each and every element of the invention to which Claim 25 is directed, Claim 25 and the Claims which depend from Claim 20 (Claims 24 and 26) should be allowed.

Claim 25 is directed to a method of handling breast milk. The steps comprise: providing a closed disposable sterile bag comprising a tear off strip; providing a bag holder; removing the tear off strip to reveal a milk receiving chamber of the bag; and mounting the bag to the bag holder. Milk is introduced into the chamber between the removing step and the mounting step or after the mounting step.

The Examiner contends that Yanase discloses a) providing a closed disposable sterile bag with a tear off strip and providing a bag holder which is a breast pump; by removing the tear off strip to reveal a milk receiving chamber; and c) mounting the bag to the bag holder/breastpump; wherein milk is introduced in said chamber between said steps b) and c) or after step c). (citing to Yanase, column 3, lines 4-33)

Contrary to the Examiner's opinion, Yanase does not disclose all of the elements of Claim 25. To illustrate, Yanase does not teach the mounting of a bag to a bag holder or breast pump. Yanase merely discloses:

"Mother's milk is collected by using a breast pump such as disclosed in U.S. Pat. No. 3,977,405 and the mother's milk contained in the breast pump can be put into the bag through said open portion as described above. The bag thus containing the mother's milk therein is closed at the open portion by the closing means and then placed in a freezer or a freezing chamber and said milk is preserved under the frozen state, for example, at a temperature below -18.degree. C."

(column 3, lines 4-33) Thus, Yanase merely teaches that milk is collected with a breastpump and then transferred into the bag through an opening in the bag. Yanase never suggests to mount the bag to the breastpump or any bag holder. Yanase teaches that the mother's milk that is put into the Yanase bag is collected by the use of a breast pump as disclosed in U.S. Patent No. 3,977,405 (the '405 patent). However, the '405 patent does not provide the deficiency of Yanase. Accordingly, even considering this added disclosure, there is no suggestion to mount the bag on a bag holder as required by present Claim 25.

- C. Independent Claims 20 and 24 Should Be Allowed Because the Examiner's Rejection Based Upon the Combined References of Graham and Yanase Do Not Provide All of the Patentably Distinguishing Features of the Invention.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) As established above, neither Graham nor Yanase teach or suggest all of the elements of independent Claims 20 and 24. For example, neither Graham nor Yanase teach or suggest “a section formed integral with said bag and located remote from said enclosure and adapted for receiving thereon information about a content of said bag.” (Claims 20 and 24) Yanase does not teach or suggest such a section or, in fact, writing any kind of information upon a bag for mother’s milk after it is filled with milk. Graham does not teach such a section of the bag located remote from an enclosure portion adapted for receiving information.

When a rejection depends on a combination of prior art references, there must be some teaching, suggestion or motivation to combine (or modify) the references. *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). Yanase utterly fails to suggest writing anywhere upon the milk bag after being filled. Graham utterly fails to suggest providing a portion of the bag for receiving information thereon. There is no teaching or suggestion to combine or modify these references to provide a portion of the bag that is remotely located from the enclosure and adapted for receiving thereon information about a content of the bag. Even *arguendo* the references were combined, as established, they would not teach the presently claimed invention.

If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) Accordingly Claims 21-23, which depend from Claim 20 should be allowed.

CONCLUSION

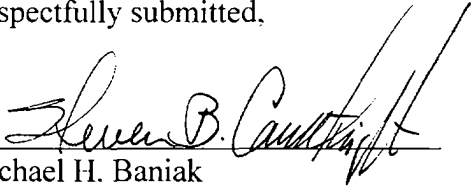
Because Graham fails to teach limitations recited in Claims 20-23, Applicants respectfully submit that the rejection of these claims under 35 U.S.C. §102 (b) should be withdrawn. Because Yanase fails to teach limitations recited in Claims 25-26, Applicants respectfully submit that the rejection of these claims under 35 U.S.C. §102(b) should be withdrawn. Because the combination of Graham and Yanase does not supply the claim limitations of Claims 20-24, nor provides a motivation or suggestion to modify the references to supply all of the claim limitations, Applicants respectfully submit that the rejection of these claims under 35 U.S.C. §103(a) should be withdrawn.

For the foregoing reasons, Claims 20-26 are patentable. Applicant respectfully request reconsideration and that the Examiner's rejections be reversed, and these Claims allowed.

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APPENDIX A

8. (Previously Amended) A bag for attachment to a breastmilk pump for containing breastmilk, the bag when flattened defining a perimeter to the bag, comprising:

- a thermoplastic film bag body having a front and back when flattened, said front and back being joined by a first seal, said first seal being a permanent seal and defining a liquid containing portion;
- an opening defined in said bag at a top of said bag through which milk is introduced into said liquid containing portion which opening is used for attachment of said bag to the breastpump;
- said first seal further defining a writing area formed integral with said bag by joining said front and back inboard of the bag perimeter in facial engagement to define said writing area, said writing area further being isolated from said liquid containing portion and located at a bottom of said bag opposite said top; and
- a pour spout formed integral with said bag and defined by said first seal, said pour spout being contiguous with an inboard side of said writing area along an inboard part of said first seal defining said writing area, whereby said inboard part of said first seal forms a stop when said pour spout is opened.

9. (Original) The bag of claim 8 further including a notch formed at the periphery of said bag and adjacent to said pour spout to tear said bag at said pour spout so that contained milk can be poured from the bag.

10. (Previously Amended) The bag of claim 8 further having a second seal, said second seal being releasable and defining said opening in said liquid containing portion for attachment of said bag to the breastmilk pump, said second seal being peeled open to form said opening.

11. (Previously Amended) The bag of claim 10 further having a tie and at least two holes formed in said bag for receiving said tie at substantially opposite sides of said opening, said two holes being isolated from said opening, whereby said tie when fit through said holes and cinched closes said opening when said bag is removed from the breastmilk pump.

12. (Previously Amended) A bag for attachment to a breastmilk pump for containing breastmilk, the bag when flattened defining a perimeter to the bag, comprising:

- a plastic film body having a front and a back when flattened and being joined to form a liquid containing portion which is initially empty of contents and hermetically sealed, said front and back being joined by a first seal line, said first seal line being a permanent seal and defining said liquid containing portion;
- a second seal line joining said front and back, said second seal line being releasable and defining an opening in said liquid containing portion, said opening being initially closed for said hermetic seal, said second seal line being peeled apart to form said opening for admission of milk into said liquid containing portion; and
- a writing area formed integral with said bag by said first seal line joining said front and back inboard of the bag perimeter in facial engagement to define said writing area, said writing area further being isolated from said liquid containing portion whereby when milk is expressed into said liquid containing portion of said bag said integral writing area remains free of milk therebelow.

13. (Original) The bag of claim 12 having a pour spout formed integral with said bag and being defined by said first seal, a notch being formed at the periphery of said bag and adjacent to said pour spout to tear said bag at said pour spout so that contained milk can be poured from said bag, said writing area having a common side with said pour spout formed by said first seal line.

14. (Original) The bag of claim 12 further including a tie, and at least two holes formed in said bag for receiving said tie at substantially opposite side of said opening, whereby said tie when fit through said holes and cinched closes said opening when said bag is removed from the breastmilk pump.

19. (Previously Added) A bag for attachment to a breastmilk pump for containing breastmilk, or for otherwise receiving breastmilk, the bag when flattened defining a perimeter to the bag, comprising:

- a thermoplastic film front sheet and a thermoplastic film back sheet, said front and back sheets being joined by a first seal, said first seal being a permanent seal and defining an initially empty liquid containing portion;
- a writing area formed integral with said bag by said first seal by further joining said front and back sheets inboard of the bag perimeter in facial engagement to define said writing area, said writing area being isolated from said liquid containing portion at a bottom end of said bag spaced from a top end opening defined in a top end of said bag through which milk is introduced into said liquid containing portion, said top end opening being also sized for attachment of said bag to a breastpump, whereby when milk is expressed into said liquid containing portion of said bag said integral writing area remains free of milk therebelow and is freely accessible for writing thereon;
- a pour spout portion formed integral with said bag and defined by said first seal, said pour spout being at said bottom end and contiguous with said writing area along an inboard side of said first seal defining said writing area, said inboard part of said first seal means forming a stop when said spout is opened;
- a second seal joining said front and back sheets adjacent said top end, said second seal being releasable and defining said opening when peeled apart, said first and second seals rendering said first and second sheets initially hermetically sealed; and

tie means for closing said opening after admission of breastmilk into said bag, said bag further having two holes formed therein for receiving said tie means, said holes being on opposite sides of said opening and isolated from said liquid containing portion.

20. (Currently Amended) A disposable bag adapted to contain breast milk, comprising a flexible closed enclosure defining a chamber adapted to contain therein breast milk, said enclosure being permanently sealed except at one portion thereof which comprises a releasable sealed seam bag access adapted to seal said bag in a first position thereof but also adapted to selectively allow in a second position thereof the breast milk to be introduced in said chamber when it is desired to use said bag, whereby once in said second position the breast milk can be received in said bag, wherein said bag includes a section formed integral with said bag and located remote from said enclosure and adapted for receiving thereon information about a content of said bag.

21. (Previously Added) A disposable bag as defined in claim 20, wherein said section comprises at least a first area for indicating thereon a date of filling of said enclosure with breast milk.

22. (Currently Amended) A disposable bag as defined in claim 21, wherein said section is capable for indicating thereon a volume of breast milk introduced in said enclosure.

23. (Previously Added) A disposable bag as defined in claim 20, wherein said bag is made from a plastic tube permanently closed at a lower end thereof by a lower seal thereby delimiting a bottom end of said enclosure, said section extending from said lower seal away from said enclosure.

24. (Previously Added) A disposable sterile plastic bag in combination with a bag holder, said bag being adapted to contain milk, said bag holder comprising a hollow body and a cap provided with a nipple and being adapted for feeding a baby, said bag holder being adapted for receiving therein said bag, said bag comprising a flexible closed enclosure defining a chamber adapted to contain milk therein, said enclosure being permanently sealed except at one portion thereof which comprises a bag access adapted to releasably seal said bag in a first position thereof but also adapted to selectively allow in a second position thereof the milk to be introduced in said chamber when it is desired to use said bag, wherein, once in said second position, a top end of said bag can be folded over an upper end of said bag holder with said cap being engageable to said upper end of said bag holder for imprisoning said top end of said bag between said cap and said upper end of said bag holder such that said bag hangs in said bag holder with milk being introduced in said bag at least one of before and after said bag is inserted in said bag holder and mounted thereto, wherein said bag includes a section formed integral with said bag and located remote from said enclosure and adapted for receiving thereon information about a content of said bag.

25. (Previously Added) A method of substantially sterilely handling breast milk, comprising the steps of:

- a) providing a closed disposable sterile bag comprising a tear off strip and providing a bag holder;
- b) removing said tear off strip to reveal a milk receiving chamber of said bag; and
- c) mounting said bag to said bag holder; wherein milk is introduced in said chamber between said steps b) and c) or after step c).

26. (Previously Added) A method as defined in claim 25, wherein after step b), said bag is attached to a breast pumping device such that breast milk retrieved by said pumping device is directly delivered through into said bag.

APPENDIX B

DISPOSABLE MILK COLLECTING
BAG FOR A BREAST PUMP

FIELD OF THE INVENTION

The present invention generally relates to breastmilk pumps, and more particularly relates to an improved bag adapted for attachment to a breastmilk pump.

BACKGROUND OF THE INVENTION

Breastmilk pumps are well known and are generally comprised of a hood that fits over the breast, a vacuum pump connected to the hood for generating an intermittent vacuum within the hood, and a receptacle for the expressed milk. There are manually driven vacuum pumps (e.g., hand-held piston pumps) which most commonly connect to at or closely adjacent to the hood, as well as vacuum pumps that are driven by an electric motor and interconnect to the hood via tubing. The vacuum pumps of these devices intermittently generate a vacuum (or a negative pressure) within the hood, with the hood encompassing the nipple and a substantial amount of the breast. The intermittent suction action of the pump serves to pull on the breast, drawing it within the narrowing funnel of the hood, to thereby extract milk in an action reminiscent of suckling. The milk so extracted typically flows from the hood into a container, e.g., a bottle, for storage and later use. A breastpump of the foregoing type is shown in U.S. Pat. No. 4,857,051.

While rigid milk containers (bottles) are most often used with breastpumps, it is also desirable to use disposable plastic bags as the containers.

SUMMARY OF THE INVENTION

One of the principal objects of the present invention is to provide a sanitary disposable bag for attachment to a breastmilk pump for containing breastmilk that can be easily and efficiently manufactured, packaged and used. To these and other ends, the inventive breastmilk bag comprises an improved flexible plastic bag adapted to contain milk, such as a bag formed by two sheets of plastic constituting a front and a back sheet that are in facial engagement and are joined to each other by a series of seals in such manner to define a hermetically sealable liquid containing portion of the bag. One feature of the invention is a writing area formed integral with the bag by the same sealing technique, but with the existing area isolated from the liquid containing portion of the bag. The bag can accordingly be written on more easily than bags with milk beneath the writing area and without risk of puncturing the milk containing portion.

Another feature of the invention resides in the liquid containing portion of the bag having an opening for attachment of the bag to the breastmilk pump, which opening is releasably sealed, as by a peelable coating, weak heat seal or other appropriate releasable fastening means such that the sealed bag can be readily peeled open for attachment to the breastmilk pump.

The inventive bag also has a tie that can be laced through at least two holes provided at substantially opposite sides of the bag opening. The laced tie is twisted upon itself to re-seal the opening when the bag is removed from the breastmilk pump, as for storage.

Yet another aspect of the invention is a pour spout formed integral with the bag and separate from the foregoing bag opening. The pour spout can be opened to pour contained milk from the bag. In a preferred embodiment, the pour spout is formed along a corner of the bag, with a notch in the side of the bag located near the

pour spout. The notch facilitates tearing of the bag to open the spout for pouring.

The inventive breastmilk bag is simple in fabrication, sanitary and disposable. It is flat, thus minimizing packaging, storage and transportation costs.

The breastmilk bag of this invention can be hermetically sealed, and thus remain sterile prior to use. In addition, after breastmilk is expressed into the bag, the bag opening can be re-sealed and the breastmilk can be sanitarily stored for later use. As previously noted, due to the provision of a writing area that is formed integral with the bag but is isolated from the liquid containing portion of the bag, there is no risk of puncturing the bag during writing, and writing is further facilitated by having a writing area that does not have liquid beneath it. When it is time to use the breastmilk, the breastmilk can easily and conveniently be poured from the bag by cutting or tearing the bag open at the pour spout.

The features and advantages of the present invention will be further understood upon consideration of the following detailed description of embodiments of the invention taken in conjunction with the accompanying drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a breastmilk bag made in accordance with the teachings of the present invention attached to a breastpump;

FIG. 2 is an exploded view of the breastmilk bag and breastpump of FIG. 1;

FIG. 3 is an enlarged plan view of the breastmilk bag of FIGS. 1 and 2 (with indicia removed);

FIG. 4 is a perspective view of a breastmilk bag substantially as shown in FIG. 3 re-sealed with a twisted tie; and

FIG. 5 is a plan view of another embodiment of a breastmilk bag made in accordance with the teachings of the present invention having a writing area that extends across the entire bottom of the bag.

DETAILED DESCRIPTION OF THE
EMBODIMENTS OF THE INVENTION

A breastpump useful in conjunction with the present invention is shown in U.S. Pat. No. 4,929,229. The disclosure of that patent is incorporated herein by reference. As will be readily recognized, however, the breastmilk bag of the present invention may be used with or adapted for many kinds of breastpumps.

As seen in the accompanying FIGS. 1 and 2, the breastpump comprises a hood body or hood member 1 having two ends. The first end 2 is funnel shaped, and during use is placed over the breast of the user. A second end 3 of the hood member communicates with a collecting or catch chamber 4, and with a vacuum line (not shown) via an extension 5. Vacuum (or lower than ambient air pressure) can be provided by an electric or manual air pump (not shown), as described in U.S. Pat. No. 4,857,051. The breastpump has a threaded collar 11 which can be used with a compatibly threaded milk bottle neck, or as described hereafter with a milk bag adapter collar 8.

At the lower portion of the collecting chamber 4 is a valve mechanism. The valve generally consists of a rigid plastic housing 12 and a thin flexible membrane 15 made of rubber or silicone rubber. The valve housing 12 has an upper section 13 and a lower section 14. The upper section 13 is cylindrical in shape, and removably engages the outer portion of the outlet (not shown) to the catch chamber 4 of the breastpump in a friction fit. The thin flexible membrane 15 has a circular shape, and is attached to the lower portion 14 of the valve housing 12 by way of a knob (not shown) which is engaged in the opening 21 in a

snap fit. The radius of the flexible membrane is large enough to completely cover the opening 22. Again, greater detail about the valve mechanism and its operation can be gleaned from U.S. Pat. No. 4,929,229.

A tubular sleeve 17 fits concentrically around valve housing 12 and is held in place via frictional engagement with the exterior of valve upper section 13. As will be seen hereafter, sleeve 17 prevents the breastmilk bag from interfering with the operation of the valve mechanism.

10 A bag 30 for containing breastmilk comprises a front sheet 32 and a back sheet 33. The front and back sheets 32, 33 are made of a suitable liquid impervious food compatible plastic, such as polyethylene. A polyethylene-polyester laminate can be advantageously used, with the polyethylene layer on the inside of the bag for flexibility, and also better sealability. Thermoplastic materials for making such disposable milk bags are well known, however. The sheets are joined by a seal 35, such as a heat seal, and a releasable seal 36. The heat seal 35 defines a writing area 45 and a liquid containing portion 40 for the bag 30. The bag 30 can similarly be formed from a continuous tube of plastic, eliminating the need for lateral seals for the bag.

14 Writing area 45 is formed integral with the bag 30, but is isolated from the liquid containing portion 40. The writing area remains flat even when the bag 30 is filled. Advantageously, indicia can be provided on the writing area designating "Name", "Date", "Time" and the like. As shown in FIG. 5, one embodiment of the present invention has a writing area 45 that extends across the entire bottom of the breastmilk bag 30.

The releasable seal 36 is released or peeled-open by pulling the front and back sheets 32, 33 away from each other in the region of the seal 36. A suitable releasable seal can be formed by the so-called zone coating technique,

whereby a material which will bond the two sheets 32, 33 together yet which is peelable is coated on one or both sheets in the area of what will be the seal 36. The seal 36 is then formed by setting the coating along the seal line. A suitable zone coating material for use with polyethylene is made by DRG Medical Packaging of Madison Wisconsin, and is an ethyl vinyl acetate resin in a solvent base applied with a gravure cylinder in a technique well known in the art. Alternatively, a weak heat seal could be used to tack the sheets together in this region, or a weak adhesive seal could be used. Release of seal 36 forms an opening in the top of the bag for attachment of the bag to breastpump 1. Portions of sheets 32, 33 are not sealed in the corners of the bag adjacent the seal 36 to facilitate opening the bag. It will be noted that the material of the bag as well as the manner of effecting the seals are entirely matters of choice, and neither form a novel part of the invention claimed herein.

To attach bag 30 to breastpump 1, the open bag top is inserted through opening 10 in adapter collar 8, and the material of the front and back sheets 32, 33 at the opening is folded over the threaded portion 9 of adapter collar 8 in an apron-like manner. Breastpump 1 is then secured to adapter collar 8 via threaded collar 11, which engages compatible threads on the adapter collar 8 pinning the apron of the bag opening therebetween.

Breastmilk bag 30 is further provided with a tie 37, which fits in two holes 38 formed at substantially opposite sides of the releasable seal 36 that forms the bag opening. When the filled bag 30 is removed from breastpump 1, the bag is slid from the adapter collar 8 and re-sealed, as by folding down the top of the bag upon itself and then twisting or cinching the ends of tie 37.

As shown in FIGS. 1-4, breastmilk bag 30 is additionally provided with a pour spout 51. Pour spout 51 is formed integral with bag 30, being defined in this

embodiment by a portion of the seal 35 of the liquid containing portion 40 which forms a side of the writing area 45. Pour spout 51 can be cut or clipped open to pour milk from the bag 30. In the preferred embodiment, however, bag 30 is additionally provided with a notch 52 at the periphery of the bag and adjacent to the pour spout 51. Pour spout 51 can thus be readily opened by tearing the bag at notch 52.

In use, milk is expressed from the breast of the user into the hood member 1, and then passes successively into catch chamber 4, valve housing 12, through hole 22, and into the breastmilk bag 30. When the user is finished, bag 30 is then removed from adapter collar 8, and the bag 30 can be re-sealed by passing the tie 37 through the holes 38, rolling down the bag in the area of the tie, and then twisting the tie together. Markings can be readily made on the writing area even after filling bag 30. The filled bag may then be stored for later use. At such later time, the milk is poured from the bag by either tearing the pour spout 51 open at notch 52, or by releasing tie 37. If a notch 52 is not provided, such as in FIG. 5, the bag 30 can simply be cut open.

Thus, while the invention has been described with reference to certain embodiments, those skilled in this art will recognize modifications of structure, arrangement, composition and the like that can be made to the present invention, yet will still fall within the scope of the invention as hereafter claimed.

The drawing shows a medical syringe (1) with a funnel (2) attached to its top. The syringe has a plunger (3) and a cap (5). The syringe is connected to a graduated bottle (4). The bottle has a cap (8) and a graduated scale (32) with markings for 1-6 oz and 50-150 mL. A label (45) at the bottom of the bottle contains fields for NAME, DATE, and TIME. Various other parts are labeled with numbers like 11, 33, 35, 51, and 52.